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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 09/491,320 | 01/26/00 | WILCOX | E MA-32CFD1 |

HM12/0816

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EXAMINER

FRONDA, C

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1652

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DATE MAILED:

08/16/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/491,320

Applicant(s)
Wilcox et al.

Examiner
Christian L. Fronda

Group Art Unit
1652



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-15 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-15 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claim Rejections - 35 U.S.C. § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 1-5, and 7-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Fraser *et al.* (US 4,870,023).

Claims 1-5, and 7-15 are anticipated by Fraser *et al.* since Fraser *et al.* teach a polyhedrin fusion protein comprising a portion of the polyhedrin protein fused to a foreign amino acid sequence (see entire patent and claim 1); the nuclear polyhedrosis virus polyhedrin protein portion is fused to the heterologous peptide by an amino acid linker (see entire patent and column 22, line 50 to column 25, line 68); and the foreign gene for use with the system include endotoxins of insect pathogenes such as the *Bacillus thuringiensis* endotoxin (see entire patent and column 39, line 54 to column 40, line 48), diphtheria toxin (see column 38, lines 53-68), and "enzymes, enzyme inhibitors, insect hormone antagonists, neurotoxins, metabolic inhibitors, insect chemattractants, endotoxins of other insect pathogens" (see column 40, lines 8-42).

Claim Rejections - 35 U.S.C. § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the

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claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4 Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over in Pennock *et al.* in view of Barnes *et al.*, Gelfand *et al.*, Stripe *et al.*, and Knowles *et al.*

Pennock *et al.* teach vectors comprising the N-terminal region of the polyhedrin gene (the major occlusion protein of the insect baculovirus *Autographa californica* nuclear polyhedrosis virus) fused to the gene encoding *E. coli* beta-galactosidase and methods of expressing said beta-galactosidase in insect cells (see entire publication); and the advantages of these vectors in expressing cytotoxic gene products (see p. 399). Gelfand *et al.* (US 4,830,962) teach a recombinant diphtheria toxin (an ADP-ribosylating enzyme) comprising the A chain and partial B chain sequence which has been truncated at the carboxyl terminus (see entire publication). Barnes *et al.* teach the production of pesticides by expression of heterologous genes such as the crystal toxin of *Bacillus thuringiensis* var. *kurstaki* HD73 (see column 2, line 1 to column 3, line 60) and the need for developing effective and environmentally acceptable pesticides (see column 1, lines 13-52). Stripe *et al.* teach ribosome-inactivating proteins including dianthin, saporin, gelonin, tritin, ricin, abrin, and modeccin from plants such as barley, rye, corn, bean, and wheat (see entire publication). Knowles *et al.* teach that a region of the endotoxin of *Bacillus thuringiensis* var. *kurstaki* recognizes and binds directly to a specific receptor present in the plasma membrane of larval midgut epithelial cells in lepidopteran insects (see entire publication).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a pesticidal protein toxin according to claims 1-15 by modifying the teachings of Pennock *et al.* in the following manner: insert the DNA encoding diphtheria toxin taught by Gelfand *et al.*, or the crystal toxin of *Bacillus thuringiensis* var. *kurstaki* HD73 taught by Barnes *et al.*, or any of the ribosome-inactivating proteins taught by Stripe *et al.* into the vector taught by Pennock *et al.* which includes a peptide linker of four or less amino acids by methods well known in the art; and express the pesticidal protein toxin in *E. coli* as taught by Pennock *et al.* One of ordinary skill in the art would be motivated to make the pesticidal protein toxin according to claims 1-15 because of the advantages of temporal regulation of expressing cytotoxic gene products as taught by Pennock *et al.* and for developing effective and environmentally acceptable pesticides as taught by Barnes *et al.* Since it is commonly known in the art that lysine is subject to proteolytic degradation, it would have been obvious to one of ordinary skill in the art to eliminate this amino acid in the peptide linker.

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Conclusion

5. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF

July 17, 2000


PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
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